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November 15, 2002

**VIA COURIER** 

The Commissioner of Patents and Trademarks
Washington, D.C. 20231
United States of America

Dear Sirs:

RE: U.S. Patent Application No. 10/030,313

Applicant: Sheena M. Loosmore

MULTI-COMPONENT VACCINE TO PRTECT AGAINST

DISEASE CAUSED BY HAEMOPHILUS

**INFLUENZAE....CATARRHALIS** 

Please find enclosed an Information Disclosure Statement and copies of the references listed therein with respect to each of the references cited in the specification, in the International Search Report received on the corresponding International application and in prior U.S. application No. 09/353,617.

Respectfully submitted,

Michael I. Stewart

Registration No. 24,973

M.I. Stewart/ac Encl.

FORM PTO-1449  U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE  STATEMENT BY APPLICANT	ATTY. DOCKET NO. 1038-1212 MIS:ac	· · · · = • · · · · · · · · · · · · · · · ·		
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## **FOREIGN PATENT DOCUMENTS**

	DOCUMENT NO.	DATE	COUNTRY	CLASS	SUBCL.	TRANSL	ATION
	WO 96/34960 x					YES	NO
	WO 94/21290X						
	WO 94/00149						
	WO 00/35477 X WO 95/34308 >						
OTHER DOCUMI			Pertinent Pages, Etc.)				
	The imp	M.L., R.T. Ma act of conjugat is. 171:93-98.	yon-White, C. Coles, I te vaccine on carriage	of <i>Haem</i>	ook, and ophilus infl	E.R. Mox luenzae ty	on. 1995. pe b. J.
	2./ Berkowitz et al. 1987. J. Pediatr. <b>110</b> :509.						
	3. Claesson et al. 1989. J. Pediatr. 114:97.				-		
	4. / Black, S.B., H.R. Shinefield, B. Fireman, R. Hiatt, M. Polen, E. Vittinghoff, The Northern California Kaiser Permanent Vaccine Study Center Pediatrics Group. Efficacy in infancy of oligosaccharide conjugate Haemophilus influenzae type b (HbOC) vaccine in a United States population of 61,080 children. 1991. Pediatr. Infect. Dis. J. 10:97-104.						
	5. / Nitta, D.M., M.A. Jackson, V.F. Burry, and L.C. Olson. 1995. Invasive Haemophilus						
	influenzae type f disease. Pediatr. Infect. Dis. J. 14:157-160.  6. Waggoner-Fountain, L.A., J.O. Hendley, E.J. Cody, V.A. Perriello, and L.G. Donowitz. 1995. The emergence of Haemophilus influenzae types e and f as significant pathogens. Clin. Infect. Dis. 21:1322-1324.						
EXAMINER:			DATE CONSIDERED:				



FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANT		ATTY. DOCKET NO. 1038-1212 MIS:ac	SERIAL NO. 10/030,313
		APPLICANT Sheena M. Loosmore et al	
		FILING DATE July 11, 2000	GROUP N/A

	NTS (Including Author, Title, Date, Pertinent Pages, Etc.)  7./ Madore, D.V. 1996. Impact of immunization on Haemophilus influenzae ty	ype b
	disease. Infectious Agents and Disease 5:8-20.	
	8. Bluestone, C.D. 1982. Current concepts in otolaryngology.	
	Otitis media in children: to treat or not to treat? N. Engl. J. Med. 306:1399-1404.	
	<ol> <li>Joannidis, J.P.A., M. Worthington, J.K. Griffiths, and D.R. Snydman. 1995 Spe and significance of bacteremia due to <i>Moraxella catarrhalis</i>. Clin. Infect. Dis. 21 397.</li> </ol>	1:390-
	10. / Meyer, G.A., T.R. Shope, N.J. Waeker, Jr., and F.H. Lanningham. 1995 More (Branhamella) catarrhalis bacteremia in children. Clin. Pediatr. 34:146-150.	
	11. Enright, M.C. and M.H. McKenzie. 1997. Moraxella (Branhamella) catarrhalis-clin and molecular aspects of a rediscovered pathogen. J. Med. Microbiol. 46:360-37	1.
	12 Barenkamp, S.J., and F.F. Bodor. 1990. Development of serum bactericida activi following non-typable <i>Haemophilus influenzae</i> acute otitis media. Pediatr. Infect. 9:333-339.	ity Dis.
	13. Barenkamp, S.J., and J.W. St. Geme III. 1994. Genes encoding high-molecular weight adhesion proteins of non-typeable <i>Haemophilus influenzae</i> are part of ge clusters. Infect. Immun. 62:3320-3328.	
	14. St. Geme III J.W., V.V. Kumar, D. Cutter, and S.J. Barenkamp. 1998. Prevalenc distribution of the <i>hmw</i> and <i>hia</i> genes and the HMW and Hia adhesins among genetically diverse strains of non-typeable <i>Haemophilus influenzae</i> . Infect. Immu 66:364-368	
	15. St. Geme III, J.W., S. Falkow, and S.J. Barenkamp. 1993. High-molecular-weigh proteins of non-typeable <i>Haemophilus influenzae</i> mediate attachment to human epithelial cells. Proc. Natl. Acad. Sci. USA 90 :2875-2879.	
	16. Barenkamp, S.J. 1996. Immunization with high-molecular-weight adhesion prote non-typeable <i>Haemophilus influenzae</i> modifies experimental otitis media in chinchillas. Infect. Immun. 64:1246-1251.	
	17 Yang, Y.P., S.M. Loosmore, B. Underdown, and M.H. Klein. 1998. Nasopharyng colonization with non-typeable <i>H. influenzae</i> , in chinchillas. Infect. Immun. 66:19 1980.	eal 73-
	18. St. Geme, J.W. and D. Cutter. 1995. Evidence that surface fibrils express Haemophilus influenzae type b promote attachment to human epithelial cells. Microbiol. 15:77-85.	Molec.
	19. × Barenkamp, S.J. and J.W. St. Geme. 1996. Identification of a second family of molecular-weight adhesion proteins expressed by non-typeable <i>Haemo influenzae</i> . Molec. Microbiol. 19:1215-1223.	philus
	20. / St. Geme, J.W., D. Cutter and S.J. Barenkamp. 1996. Characterization of the glocus encoding Haemophilus influenzae type be surface fibril. J. Bact. 178:6281-	enetic 6287.
EXAMINER:	DATE CONSIDERED:	

\*EXAMINER: Initial if r ference considered, whether or not citation is in conformanc with MPEP 609; Draw line through citation if in conformance and not considered. Includ copy of this form with n xt communication with applicant.

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			FILING DATE July 11, 2000	GROUP N/A		

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)				
OTHER BOCO	21./	Retzlaff, C., Y. Yamar Bacterial heat shock	moto, P.S. Hoffman, H Friedman, and T.W. Klein. 1994. proteins directly induce cytokine MRNA and interleukin-1 e cultures. Infect. Immun. 62:5689-5693.	
	22.,	Loosmore, S.M., Y-P. Y	ang, R. Oomen, J.M. Shortreed, D.C. Coleman, and M.H. ophilus influenzae HtrA protein is a protective antigen. Infect.	
	23.		ey, M. 1981. A rapid boiling method for the preparation of . Biochem. 114:193-197.	
	24. /	Tabor S. and Richardson system for controlled extended 82(4): 1074-1078.	n C.C., 1985. A. bacteriophage T7 RNA polymerase/promoter clusive expression of specific genes. Proc. Natl. Acad. Sci.	
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<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if in conformance and not considered. Include copy of this form with next communication with applicant.